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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,350	12/09/2003	Jens Aage Munk	6485.200-US	3540
23650	7590	01/30/2006		
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			EXAMINER	SUNDARARAMAN, VIKRAM P
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/731,350	MUNK, JENS AAGE
	Examiner Vikram P. Sundararaman	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: (a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al, US 6,175,752 B1, hereinafter referred to as Say, in view of Kurnik, US 6,546,269 B1, hereinafter referred to as Kurnik.

3. As to **Claim 1**, Say teaches "methods and devices for the continuous and/or automatic in vivo monitoring of the level of an analyte [such as glucose]" (a continuous blood glucose monitor), comprising:

a "sensor, a sensor control unit, and a display unit," [Abstract, Line 1-2] wherein "the sensor control unit... may also include a variety of optional components, such as, for example... a processing circuit," [Column 2, Lines 26-29] and "the analyte monitoring system also includes a display unit that has a receiver for receiving data from the sensor control unit and a display coupled to the receiver for displaying the indication of the level of an analyte," [Column 2, Lines 46-50]. (a display; a processor that is

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interfaced with the display; the processor being configured to display data on the display)

a display wherein "the display may contain more complex structures, such as LCD or LED alphanumeric structures, portions of which can be activated to produce a letter, number, or symbol," [Column 50, Lines 42-44] and "the display may also be capable of displaying a graph of the analyte over a period of time," or "graphs of the rate of change or acceleration in the rate of change of an analyte level over time" [Column 51, Lines 4-8]. (the data being displayed in a graphical form, as a single image, past and present glucose values and trend data). It is inherent that a graph of an analyte over time would necessarily include both past and present analyte values as only in this case would there be scope to graph rates of acceleration in rate of change of analyte concentration over time.

What Say fails to teach is a processor further being configured to calculate future blood glucose values. Kurnik teaches "a method and device provided for measuring the concentration of target chemical analytes present in a biological system, and then predicting a future or past concentration of an analyte using a series of such measurements" [Abstract, Lines 1-4]. Kurnik teaches that prediction of future values is beneficial to correct for any discrepancies between the measured glucose level and the actual (real-time) glucose level from the lag-time between extracting the glucose analyte and obtaining a measurement from the extracted glucose, for example in the case of continuous monitoring of glucose analyte level using iontophoresis. Kurnik also teaches that prediction of future values may be used to control an aspect of the

biological system, particularly a physiological effect. In view of the teachings of Kurnik, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Say to include the elements as disclosed by Kurnik to provide a processor configured to calculate future blood glucose values and to display the future values simultaneously with the past and present data in the same image, since Say already presents future indicators based on for example trend and/or threshold analyses.

4. As to **Claim 2**, Say teaches, "one example of a receiver/display unit is illustrated in FIG. 23. The display of this particular receiver/display unit includes a portion which displays the level of the analyte, for example, the blood glucose concentration, as determined by the processing circuit and/or the analyzer using signals from the sensor. The display also includes various indicators which may be activated under certain conditions. For example, the indicator of a glucose monitoring device may be activated if the patient is hyperglycemic. Other indicators may be activated in the cases of hypoglycemia, impending hyperglycemia, impending hypoglycemia, a malfunction, an error condition, or when a calibration sample is needed." Say further teaches that "in some embodiments, color coded indicators may be used" and furthermore that "the portion which displays the blood glucose concentration may also include a composite indicator, portions of which may be appropriately activated to indicate any of the conditions described above" [Column 50, Lines 53-67 and Column 51, Lines 1-3]. (The processor is further configured to display a visual indication as to whether the blood

glucose level is predicted to be at an acceptable level at a predetermined time in the future, the indication comprising displaying the image in a first color for good and a second color for bad)

5. **Claims 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of Kurnik, as described above in Paragraph 3 and Paragraph 4.

6. As to **Claim 4**, items 4a (a means for showing the present value of a parameter), 4c (a means for showing whether the monitored parameter has been relatively constant for a predetermined past period, whether the parameter value is increasing or decreasing, and the relative rate at which the parameter is changing, and (wherein the means a-c are displayed in a graphical form in a single viewing of the display) are described by the combination of Say and Kurnik as described in Paragraphs 3 and 4 of this action. Say further teaches that "the display also includes various indicators, 166, which may be activated under certain conditions. For example... a malfunction, an error condition, or when a calibration sample is needed, 176." [Column 50, Lines 58-65]. (b. a means for showing information about the monitoring device).

7. **Claims 5-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of Kurnik, as described above in Paragraph 3 and Paragraph 4.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 730am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert S. Mason
ROBERT S. MASON
EXAMINER

VPS